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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,968	08/26/2003	Helmut Borberg	07030.0004U2	7077
23859 7590 08/22/2008 Ballard Spahr Andrews & Ingersoll, LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER WIEST, PHILIP R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 08/22/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/649,968

Applicant(s)

BORBERG ET AL.

Examiner

Phil Wiest

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) 1 and 2 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on 26 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The ~~affidavit~~ from Helmut Borberg under 37 CFR 1.132 filed 4/22/08 is insufficient to overcome the rejection of claims 1 and 2 based upon the 103(a) rejection over Georgazde in view of Makchesky and Hunter as set forth in the last Office action because: the affidavit lacks evidence in support of the inventor's statements. No reason is stated why one would not have been motivated to remove high molecular weight proteins to treat diabetic ischemia. It has been held that one of ordinary skill in the art is also one of ordinary creativity in the art, not an automaton. See *KSR Int'l. v. Teleflex*, 550 U.S. ___, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). Taken together, the references reasonably suggest such an approach to providing patient therapy.

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The affidavit further lacks any objective evidence why there's no reasonable expectation of success if one attempted to filter high molecular weight proteins from the blood to treat diabetic ischemia. Applicant is claiming just such a process, which he asserts is successful. Such a disclosure indicates a reasonable expectation of success.

Additionally, while publication in scientific journals may indicate the success of a procedure, the mere publication of a particular technique, absent any evidence of unexpected results over the prior art techniques, is not a valid measure of unobviousness.

The affidavit also states that the cited prior art does not present specific data or evidence on the research of hemorheology to explain the clinical efficacy of the healing

of diabetes. This is not persuasive because no data on clinical efficacy is required to establish a *prima facie* case of obviousness.

Finally, the affidavit states that the same treatment technology was accepted as a US patent (US 6,627,151) for the treatment of ophthalmologic diseases and small vessel disease. This statement, however, is irrelevant. The previously issued patent relates to a method of treating small vessel disease in the heart, while the instant claims are drawn to a method of treating ischemia in the foot. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

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2. The declaration from Paul Hoecker under 37 CFR 1.132 filed 4/22/08 is insufficient to overcome the rejection of claims 1 and 2 based upon 103(a) as set forth in the last Office action because: The declaration, while proffering the opinion of one of ordinary skill in the art, lacks any evidence to support that the claimed method is widely known. Furthermore, the simple fact that the method is widely known does not have any bearing on whether the method is obvious over other disclosures in the art. The declaration asserts that the method is unique, but fails to provide a nexus between the "therapeutic approach" and the steps of the claimed invention.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

3. Applicant's arguments filed 4/22/08 have been fully considered but they are not persuasive. Applicants argue that the combination of Georgadze, Malchesky, and Hunter 35 U.S.C. 103(a) would not have been obvious to one of ordinary skill in the art at the time of invention. The examiner disagrees.

4. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Georgadze generally teaches plasmapheresis used to treat ischemia in the lower extremities of diabetics, Malchesky teaches the plasmafiltration of blood for the removal of high molecular weight protein for the treatment of hyperviscosity syndromes, and Hunter teaches that ischemia causes hyperviscosity of the blood, thereby resulting in circulatory disturbances (see the rejection below). Therefore, Hunter provides motivation to use the high molecular weight plasmafiltration method of Malchesky with the Georgadze's method for treating ischemia of the lower extremities, because doing so would prevent hyperviscosity, thereby preventing circulatory disturbances.

Art Unit: 3761

5. Applicant's arguments regarding the affidavit and declaration filed 4/22/08 have not been found persuasive. See discussion above. It has been held that one of ordinary skill in the art is also one of ordinary creativity in the art, not an automaton. See *KSR Int'l. v. Teleflex*, 550 U.S. , 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). Taken together, the references reasonably suggest such an approach to providing patient therapy.

6. Finally, applicant argues that clinical success and publication in a peer review journal demonstrates nonobviousness. This argument has not been found persuasive. Simply because a treatment is effective does not mean that it was not obvious given the state of the art at the time of invention. The removal of high molecular weight proteins to treat ischemia has the same effect as suggested by Malchesky and Hunter. Additionally, mere publication in a peer review journal is by no means evidence that the combination of the cited prior art references is not obvious.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1 & 2 are rejected under 35 U.S.C. 103(a) as obvious over "*Plasmapheresis in the treatment of critical degree of ischaemia in diabetic and angiopathies of lower extremities*" (Georgadze et al.) in view of Malchesky et al. (4,350,156), and further in view of Hunter (US 5,152,979)

Georgadze et al. teaches that plasmapheresis may be used for the treatment of ischemia in the lower extremities of diabetics. It is disclosed that the plasmapheresis corrects the biochemical and coagulation parameters of the blood and thereby preserves the extremity from amputation in most patients. Plasmapheresis will remove protein, as disclosed in the article (see chart & body of article). The treatment of blood via plasmapheresis as treatment for a person diagnosed with diabetic ischemia of the foot since the foot is met since a foot is obviously part of the lower extremity. Such treatment would be beneficial to preserve the foot from amputation. Georgadze et al. substantially teaches the invention as claimed, except for specifically teaching that the method to remove high molecular weight proteins and wherein the high molecular weight protein is lipoprotein cholesterol.

Malchesky et al. teaches of plasmafiltration of blood for the removal of high molecular weight proteins (for example 100,000 Daltons) such as cholesterol-lipid complexes (i.e. lipoprotein cholesterol). The removal of high molecular weight proteins has a variety of treatment benefits, such as treating various diabetes-related ailments and hyperviscosity syndromes (Column 1, Line 23 through Column 2, Line 8).

Hunter generally teaches that ischemia causes increased viscosity of blood and recognizes that increased whole blood viscosity is capable of causing serious circulatory disturbances (Column 3, Lines 63-68)

Therefore, it would have been obvious to one at the time of the invention, since the procedures of plasmapheresis of blood and plasmafiltration of blood are analogous fields of endeavor, to modify the method of Georgadze et al. to specifically remove high molecular protein, such as lipoprotein cholesterol, as taught by Malchesky et al. since both teach of removing protein from the blood to achieve a therapeutic result, such as returning blood to its normal viscosity. Hunter clearly teaches that ischemia causes impaired circulation because of blood hyperviscosity, and therefore provides motivation to prevent ischemia by Malchesky's method of viscosity control.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3761

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235.

The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

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//Leslie R. Deak//
Primary Examiner, Art Unit 3761
18 August 2008

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